MAR 0 8 2013

Dräger

K123776

510(k) summary

As required per CFR 21 807.92

General Company Information

Submitters Name and Address: Dräger Medical GmbH
Moislinger Allee 53-55,
D-23542 Luebeck, Germany

Manufacturer`s Name and Address: Dräger Medical GmbH
Moislinger Allee 53-55,
D-23542 Luebeck, Germany

Establishment Registration Number: 9611500

Contact Person:

Mr. Ulrich Schroeder
Moislinger Allee 53-55,
D-23542 Luebeck, Germany
Phone : 49 (451) 882-3648
Fax :49 (451) 882-3018
Email: Ulich.Schroeder@draeger.com

Alternate

Mrs. Beth Zis
Draeger Medical Systems, Inc., 6 Tech Dr,
Andover, MA 01810
Phone +1 (978) 3798255
Fax: +1 (978) 3798335
Email: beth.zis@draeger.com

Device Name

Common Name:	Lamp, surgical
Legally Marketed Device Identification:	Polaris 100/200
Regulation Number	878.4580
Regulation Description	Surgical Lamp
Regulation Medical Specialty	General & Plastic Surgery
Product Code	FTD
Class	2

Device description:

The Polaris 100/200 light is designed for use in as an operating light. For the Polaris 100/200 light, LED bulbs are used.
The Polaris 100 light combines the illumination intensity of 48 white LED bulbs, the Polaris 200 light combines the illumination intensity of 66 white LED bulbs to form a homogeneous illumination volume of considerable illumination depth and low shadiness. A color temperature similar to natural light with good color rendering and dimmable illumination intensity ensure working conditions for surgical and treatment procedures.

Indications / Intended Use:

Polaris 100/200 lights are classified as operating lights in accordance with IEC 60601-2-41 and are intended to be used for the local illumination of the surgery and treatment area on the patient in operating and treatment rooms.
Double light
The combination of two operating lights as an operating light system enables the use in operating and treatment rooms.
Versions
– Polaris 100 light
– Polaris 200 light

Legally marketed devices:

Dräger is claiming substantial equivalence of its Polaris 100/200 surgical light to the Sola 700, Sola 500 from Dräger (K010724) and to the device iLED from Trumpf Medizin Systeme (K061317).

Technological Characteristics:

Performance testing was conducted to verify that the proposed Polaris 100/200 Surgical lamp meet the requirements for Medical Electrical Equipment as defined in IEC 60601-1 and IEC 60601-2-41

Substantial Equivalence:

The proposed device Polaris 100/200 and all predicative devices have the similar intended use and they conform to the same particular standard: IEC 60601-2-41. In addition the iLED and the new Polaris 100/200 do use the same light source / technology: light emitting diodes (LED).

There are differences in design and operation but these do not alter the safety or efficacy of the device.

Dräger is claiming its Polaris 100/200 surgical light to be as safe, as effective, and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Drager Medical GMBH
% Draeger Medical Systems, Incorporated
Ms. Beth Zis
Director, Regulatory Affairs
6 Tech Drive
Andover, Massachusetts 01810

Re: K123776
Trade/Device Name: Polaris 100/200
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FTD
Dated: December 04, 2012
Received: December 10, 2012

Dear Ms. Zis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Polaris 100/200 lights are classified as operating lights in accordance with IEC 60601-2-41 and are intended to be used for the local illumination of the surgery and treatment area on the patient in operating and treatment rooms.

Double light

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Versions

– Polaris 100 light

– Polaris 200 light

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.03.08 11:00:35 -05'00'

(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number ___K123776_____